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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,145	10/19/2001	Michel Pairat	1/1174US	4148

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EXAMINER

BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/26/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,145

Applicant(s)

PAIRET ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-10,15-23,25-39,59,60 and 63-66 is/are pending in the application.

4a) Of the above claim(s) 59-60 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-10,15-23,25-39 and 63-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and remarks submitted 2 June 2003 are acknowledged.

This application contains claims 59-60 drawn to an invention nonelected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment and remarks have overcome the rejection under 35 USC 112 in the previous office action.

Claim Objections

Claims 3-4, 7-8, 10, 16-17, 25-26, 29, 30, 32, 36-37 are objected to as being directly or indirectly dependent from cancelled claim 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39 and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (*Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma*, 1999) in view of Banholzer et al. (USPN 5,610,163).

Nishimura et al. teaches an inhalation composition comprising oxitropium bromide and an inhalation composition comprising beclomethasone employed in treating asthma, see in particular pages 85-86. Nishimura also broadly teaches that the addition of inhaled anticholinergic agents (e.g., ipratropium bromide or oxitropium bromide) to corticosteroids has been recommended in the treatment of asthmatic patients, see col.2 of page 85 and col. 1 of page 87 in particular.

Nishimura et al. does not teach tiotropium salts as anticholinergic agents, useful in asthma treating compositions. Neither does it teach a kit.

Banholzer et al. (USPN 5,610,163) teaches an inhalation composition comprising the anticholinergic agent tiotropium salt (e.g., bromide) useful in treating asthma, see abstract, claims 1 and 14 in particular.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ tiotropium bromide in lieu of ipratropium bromide or oxitropium bromide in the composition of Nishimura et al. and to incorporate the resulting composition in a kit.

One of ordinary skill in the art would have been motivated to employ tiotropium bromide in lieu of ipratropium bromide or oxitropium bromide in the composition of Nishimura et al. because tiotropium, like ipratropium and oxitropium, is an anticholinergic agent readily used in inhalation compositions useful for treating asthma. Note that the incorporation of a

pharmaceutical composition into a kit with a set of instructions is within the purview of the Skilled Artisan and is therefore obvious.

Claims 1, 3-5, 7-10, 15-23, 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al. (*Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma*, 1999) in view of Banholzer et al. (USPN 5,610,163) as applied to claims 39 and 63-66 above and further in view of Gennaro et al. (*Remington's Pharmaceutical Sciences*, 18th ed., 1990, pages 1694-1699 and 1706-1707).

Nishimura et al. (*Additive effect of oxitropium bromide in combination with inhaled corticosteroids in the treatment of elderly patients with chronic asthma*, 1999) and Banholzer et al. (USPN 5,610,163) do not teach the employment of the specific excipients, co-solvents, herein. Neither do they teach the specific particle sizes claimed herein.

Gennaro et al. (*Remington's Pharmaceutical Sciences*, 18th ed., 1990, pages 1694-1699 and 1706-1707, 1709) teaches the employment of excipients/pharmaceutical necessities in inhalers. It also teaches the particle sizes herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific excipients and the particle sizes herein.

One of ordinary skill in the art would have been motivated to employ the specific excipients and particle sizes herein, because the pharmaceutical necessities and the particle sizes employed herein are all known to be useful in inhaler compositions. Absent a showing of criticality, the employment of pharmaceutical necessities is within the purview of the skilled artisan and is therefore obvious. No such showing has been proffered.

Response to Arguments

Applicant's arguments filed 2 June 2003 have been fully considered but they are not persuasive. Applicant argues that the physical and chemical differences between ipratropium and oxitropium bromide and tiotropium bromide would militate against the combination of beclomethasone and tiotropium. Note that ipratropium, oxitropium bromide and tiotropium are all known anticholinergic agents. Further note that as shown in the body of the rejection all three are known to be useful in treating asthma by targeting the same mechanism, therefore they are equivalents of one another, absent evidence to the contrary. No such evidence is seen.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The

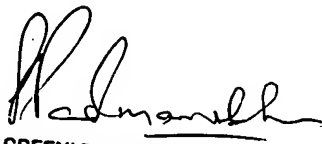
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examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
August 18, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 8/25/03